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No. 06-1582

IN THE

Supreme Court of the United States

PFIZER INC.,

Petitioner,

v.

APOTEX, INC. (formerly known as TorPharm, Inc.),

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY FOR PETITIONER

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REPLY FOR PETITIONER

Three judges, dissenting from the denial of rehearing *en banc* in this case, decried the grave consequences the panel decision will have for pharmaceutical patents. Pet. App. 41a-51a. Yet the judgment embodied in that panel decision was reached without benefit of this Court's later-decided opinion in *KSR International Corp. v. Teleflex Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (2007). Respondent nonetheless claims that the Federal Circuit must have "read [that] decision" (Opp. at 5), and "was fully aware of *KSR*" (*id.* at 6), in the course of silently rejecting Pfizer's *en banc* petition. But as this Court outlined in *Lords Landing Village Condominium Council of Unit Owners v. Continental Insurance Co.*, 520 U.S. 893 (1997), even where a lower court makes an "ambiguous statement" about the effect of an intervening decision—which surely demonstrates that the lower court has "read" and "was fully aware of" the new decision—that is not enough to avoid the need for a GVR order. *See* pp. 2-4, below.

Respondent is also wrong to say that "Pfizer does not claim that this case merits plenary review." (Opp. at 4) Pfizer does so claim, and the case does merit plenary review. *See* Pet. at 8 ("The importance of the issues in this case . . . would surely qualify this case for plenary review."); *see also* Br. *Amicus Curiae* of Wash. Legal Found. at 2 ("*Amicus* Br."). But Pfizer seeks GVR not merely because of the Federal Circuit's inexplicable silence in the wake of the milestone *KSR* decision, but also because Pfizer's remaining rights under the '303 patent evaporate on September 25, 2007. *See* Pet. at 16; Pet'r's Supp. Br. at 1-2. GVR is the only meaningful opportunity Pfizer has to secure any review of this decision at this point, lest the case become moot by the passage of time.

If the case does become moot, then, as Pfizer showed (Pet. at 16-19), the Federal Circuit's judgment should be vacated under *United States v. Munsingwear, Inc.*, 340 U.S. 36

(1950), and *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994). If that happens, Respondent would retain a case-specific victory on mootness grounds. But apparently that is not enough for Respondent, which now argues *against* a mootness victory by suggesting that Pfizer's pediatric exclusivity period may not actually end on September 25, 2007, and that Pfizer may be entitled to relief, including monetary damages, beyond that date. Respondent is wrong to suggest those theories, which are blocked by statute and by this Court's own precedents, even though Pfizer would otherwise welcome that possibility. *See* pp. 5-8, below.

As we showed in the Petition, and show again below, vacatur of the Federal Circuit's decision—whether because of the Federal Circuit's failure to give proper consideration to *KSR* or on mootness grounds—is the appropriate course here.

* * * *

1. Despite the Federal Circuit's telling silence on the issue, Respondent claims that "the court of appeals ... has already considered *KSR*" in this case, because it must have "read" (Opp. at 5) and been "fully aware of *KSR*" (*id.* at 6), and that "there is no tension between the holding below and [] *KSR*." *Id.* Those claims cannot withstand scrutiny.

Obviously, the March 22, 2007 panel decision could not have considered *KSR*, which this Court issued on April 30, 2007. *See* Pet. at 6. And suppositions that the judges of the Federal Circuit were "aware of" or had "read" *KSR* while the *en banc* petition was still pending are not enough to dispel the need for a GVR order. In *Lords Landing Village Condominium Council of Unit Owners v. Continental Insurance Co.*, 520 U.S. 893 (1997), resolution of the case turned on a state-law question. After the federal court of appeals decided the state-law question and issued its mandate, the state supreme court announced a new decision calling the circuit court's resolution of the state-law issue

into doubt. There, as here, the parties made the appeals court aware of the decision. Indeed, in *Lords Landing*, the court of appeals issued a written order whose sole purpose was to discuss whether the new decision "required a different disposition of this case." *Id.* at 898 (Rehnquist, C.J., dissenting) (describing lower court's order). So the court of appeals there had unquestionably "read" and was "aware of" the intervening decision.

This Court nonetheless entered a GVR order: The intervening decision provided "reason to question the correctness of the Court of Appeals' decision," and "the Court of Appeals' ambiguous statement that petitioner's request was 'without merit' does not establish that it actually considered and rejected petitioner's . . . argument" based on the intervening decision. *Id.* at 896-97. Here, the Federal Circuit stood entirely silent on the effect of *KSR*. And that silence, even more than the Fourth Circuit's "ambiguous statement" in *Lords Landing*, "does not establish that it actually considered and rejected petitioner's . . . argument" regarding *KSR*. *Id.* at 897. *See also Thomas v. Am. Home Prods., Inc.*, 519 U.S. 913, 915 (1996) (Scalia, J., concurring).

Nor can Respondent sidestep the need for a GVR order by the oversimplified claim (Opp. at 7) that *KSR* "broadened the defense of obviousness" in comparison to the Federal Circuit's earlier tests. For one, *KSR* itself declared that question to be "a matter for the Court of Appeals to consider in its future cases." 550 U.S. at ___, 127 S. Ct. at 1743. For another, the Federal Circuit's first post-*KSR* obviousness decision, *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007), did not apply *any version* of the controversial teaching-suggestion-motivation test that served as the basis for the Federal Circuit's decision here. That leaves substantial doubts about the continued validity of the panel decision's reasoning in this case. *Compare id.* at 1161-62 *with* Pet. App. 18a-23a. Finally, even if one considers *KSR* to have "broadened" the obviousness defense,

that is not necessarily true across the board, as Pfizer showed in the Petition (at 12-14): Much of this Court's *KSR* opinion focused on when combined elements work together in an "unexpected and fruitful manner." 550 U.S. at ___, 127 S. Ct. at 1740 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)). Such "surprising results" were not present in the simple mechanical device at issue in *KSR*, but they are often—as the district court here found (Pet. App. 10a-11a)—present in chemical and pharmaceutical inventions. *Amicus* WLF sets forth a number of the district court's findings in this respect (*Amicus* Br. at 4-5); the Federal Circuit should apply the rulings of *KSR* to these facts expressly, not (as Respondent claims) *sub silentio*.

The Court's similarly silent denial of certiorari in *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 75 U.S.L.W. 3661 (U.S. June 11, 2007) (No. 06-1207), likewise does not mean, as Respondent claims (Opp. at 9), that the "this Court has already recognized" that *DyStar* (and by extension this case, which relied on *DyStar*) is consistent with *KSR*. It is "well-settled" that "denial of certiorari imparts no implication or inference concerning the Court's view of the merits," *Hughes Tool Co. v. Trans World Airlines, Inc.*, 409 U.S. 363, 365 n.1 (1973), and it bears further note that DyStar's petition neither sought GVR nor presented the question at the heart of this case; rather, it presented three other diffuse questions—one about the Seventh Amendment, one factbound question about the objective indicia of nonobviousness in that case, and a third regarding a supposed "new corroboration requirement for all testimony in patent cases." Pet. for Cert. at i, *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, No. 06-1207, 2007 WL 683959 (Mar. 5, 2007). Particularly in that light, no inferences can or should be drawn from the denial of certiorari in *DyStar*.

KSR made important changes to the law of obviousness. The Federal Circuit should have at least attempted to square a decision with such broad ramifications and severe

consequences with *KSR*. That is precisely what the GVR remedy is designed to accomplish.

2. In the alternative, Pfizer has urged the Court—if it is unable to review this case prior to September 25, 2007—to grant the petition and vacate the decision below under *Munsingwear* and *Bonner Mall*, because the expiration of Pfizer's pediatric exclusivity on that date will end the last legal right Pfizer has associated with the '303 patent. *See* Pet. at 16-19.

Although this alternative remedy would leave Respondent with a victory in this particular dispute (because Respondent is now competing in the market with a generic version of Pfizer's Norvasc®, and would stay in the market unaffected), that is seemingly not enough. Respondent has now suggested (without "intend[ing] to concede" anything, *see* Opp. at 12) that this case may not become moot on September 25, 2007, when Pfizer's pediatric exclusivity ends, because, *inter alia*, there are theories under which Pfizer might sue Respondent. Respondent's newly crafted theories are unavailing, and do not stand in the way of vacatur for mootness.

There is no realistic possibility that Pfizer will be able to obtain monetary or other relief under Respondent's theories. The pediatric-exclusivity period that Pfizer has lost by this decision does not extend the patent term. *See* 21 U.S.C. § 355a(c)(2)(B) ("the period during which an application may not be approved . . . shall be extended by a period of six months *after the date the patent expires* (including any patent extensions)") (emphasis added). And, as this Court has held, the Food, Drug and Cosmetic Act (FDCA) "leaves no doubt" that private litigants may not sue for noncompliance. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). So it is not feasible that a controversy will continue to exist in this case after September 25, 2007.

Indeed, the fact that Respondent is now positing a number of theories under which it might be liable for hundreds of millions of dollars in damages is a strong indication that Respondent does not seriously believe any of them has merit. In fact, Respondent's own descriptions of these theories of recovery acknowledge just how dubious they are, with its choice of words emphasizing the shaky foundation on which they are constructed. *See* Opp. at 9 ("far from clear"), 10 ("far from clear" and "perhaps" both repeated twice), 11 ("perhaps" repeated three times; "[t]o be sure, nothing in the applicable statute expressly grants a patentee a right of action against competitors . . . [s]till, an implied right of action could be derived from the statute"), 12 ("the FDA might itself choose to revoke the right of generic competitors to market their drugs for a period of time in order to grant Pfizer a full six months of exclusivity"). Respondent itself summarizes the nature of its suggested remedies in these words: "To be sure, . . . whether Pfizer might have some remedy after September 25 . . . is unclear; we have no confidence in the outcome of that inquiry." Opp. at 12.

But all of Respondent's theorizing about other claims that Pfizer "might," "perhaps" bring in the future can be swept to the side, because they are far different than the infringement claim that Pfizer brought in this case. And "[t]he mootness of petitioner['s] claim at the present stage of the proceedings must be assessed on the basis of what that claim *is*." *Grupo Mexicano de Desarrollo S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 315 n.2 (1999) (emphasis in original).*

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* Even if Respondent's newly hypothesized claims *were* feasible ones, which they are not, and *were* present in this case, which they are not, vacatur and remand would still be the appropriate course. *See, e.g., Diffenderfer v. Cent. Baptist Church of Miami, Fla., Inc.*, 404 U.S. 412, 415 (1972) (remanding case, which had become moot by the Florida legislature's repeal of the challenged statute and replacement with a different one, because plaintiff might wish to amend its complaint "to

Notwithstanding Respondent's contrary contentions (Opp. at 13-14), the equities here only favor vacatur. Pfizer has attempted to protect its remaining rights with vigor and promptness. The decision below is of questionable merit: No court has even *attempted* to square that decision with *KSR*, and it rests on shaky legal foundations as underscored by not one, not two, but three separate district courts having found that the patented invention here was not obvious. *See* Pet. at 1 n. *, 18 (noting the *Mylan* and *Synthon* cases, both of which have now been reversed by the Federal Circuit based on the preclusive authority of the panel decision below). If left standing without the opportunity for further review, it will "call[] into question countless pharmaceutical patents, which in turn could have a profoundly negative effect on investments into the design and development of new life-saving pharmaceuticals." Pet. App. 51a (Rader, J., dissenting from the denial of rehearing *en banc*).

Against all of these equitable factors stand only (i) Respondent's unsupported (and demonstrably incorrect) suggestion that Pfizer's is a "worthless ... petition for certiorari" (Opp. at 13), which is, at minimum, offensive to the three dissenting judges in the Court of Appeals, and (ii) Respondent's bizarre claim that because Justice Stevens denied (without comment) Pfizer's application to recall the mandate, that act somehow simultaneously disentitled Pfizer from the equitable relief of vacatur. *Id.* at 14.

Respondent has failed to identify any way in which it or the public would be harmed either by a GVR order or by an order vacating the decision below under *Munsingwear*. The harm to Pfizer, and to the public, by contrast, is manifest. Pet. at 14-15; *Amicus* Br. at 1-2. It would be wrong to saddle

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demonstrate that the repealed statute retains some continuing force or to attack the newly enacted legislation").

the pharmaceutical industry, and by extension the public that relies on those pharmaceuticals, with an unworkable and incorrect rule of law on obviousness merely because the rights associated with the '303 patent expired before this Court had an opportunity to undertake review.

CONCLUSION

For these reasons, and those set forth in the Petition, the petition should be granted, and the judgment of the Court of Appeals vacated.

Respectfully submitted,

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